Exponent®

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February 1, 2008

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428 Attn: TSCA Section 8(e) Coordinator
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Contain NO CBI

Re: Nonylphenol Ethoxylate (NPE) Phosphates and Sulfate Derivatives
CAS # 9014-90-8

TSCA Section 8(e) Coordinator:

On behalf of our client the Joint Inerts Task Force (JITF) Cluster Support Team 9 (JITF CST 9) (1156 15th St. N.W., Suite 400, Washington, D.C. 20005), Exponent, Inc. is submitting information pursuant to the provisions of Section 8(e) of the Toxic Substance Control Act (TSCA). The JITF CST 9 includes the following member companies: BASF Corporation, Bayer Crop Science, Cognis, FMC Corporation, Nufarm Americas, Rhodia, Inc., Stepan Company, and Syngenta.

The following information is a summary of available data that are being reported under TSCA Section 8(e):

The JITF CST 9 is conducting a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening Test (OECD 442 – OPPTS 870.3650) using CAS # 9014-90-8 as the test substance.

Dose Selection

In order to set appropriate dose levels for an OECD 422 definitive study and to determine the maximum tolerated dose (MTD), a range-finding study was carried out, administering the test substance by oral gavage to groups of 3 male and 3 female rats at doses of 0, 100, 300 and 1000 mg/kg/day. Doses were adjusted using a correction factor of 3.25 to account for purity of the test substance (30.76%) for the purpose of dose calculation.

Study Results

In the OECD 422 range-finding study, males were treated over a 14-day pre-pairing period, during the pairing period and up to one day before necropsy (for a total of 28 days of treatment). Females were treated throughout the pre-pairing, pairing and gestation period up to day 13 post

coitum. For evaluation of fertility, the number and distribution of implantation sites, live or dead embryos, and early and late embryonic deaths in each uterine horn were recorded.

All animals survived until the scheduled sacrifice and no significant clinical signs were noted during the study. Body weight and food consumption data showed slight reductions only at 1000 mg/kg/day, seldom attaining statistical significance for specific days in females only, and limited to the pre-pairing period.

All females in all groups were found to be pregnant. The pre-implantation loss was statistically significantly higher at 300 mg/kg/day. Consequently, the number of implantation sites and the number of live embryos was reduced at this dose.

The following table summarizes the available data.

Parameter	**Control**	**100 mg/kg/day**	**300 mg/kg/day**	**1000 mg/kg/day**
Number of dams	3	3	3	3
Corpora lutea	46	44	43	51
Mean ± SD	15.3 ± 0.6	14.7 ± 1.5	14.3 ± 2.5	17.0 ± 2.6
Pre-implantation loss	0	2	5	3
% of corpora lutea		4.5	11.6*	5.9
Mean ± SD		0.7 ± 1.2	1.7 ± 2.9	1.0 ± 1.7
No. of dams affected		1	1	1
Implantation sites	46	42	38	48
% of corpora lutea	100.0	95.5	88.4*	94.1
Mean ± SD	15.3 ± 0.6	14.0 ± 2.6	12.7 ± 4.0	16.0 ± 2.6
Post-implantation loss	3	1	4	2
% of implantation sites	6.5	2.4	10.5	4.2
Mean ± SD	1.0 ± 1.0	0.3 ± 0.6	1.3 ± 2.3	0.7 ± 0.6
No. of dams affected	2	1	1	2
Total embryos	43	41	34	46
% of implantation sites	93.5	97.6	89.5	95.8
Mean ± SD	14.3 ± 0.6	13.7 ± 3.2	11.3 ± 6.0	15.3 ± 2.3
Live embryos	43	41	34	46

* Fisher's exact test significant at level 5%

JITF CST 9 is also reporting that the effects on pre-implantation loss and the resulting other effects may not be compound or treatment-related because the effect is limited to the middle dose group. No significant effect was observed in the high dose group, which received more than three times the dose of the middle dose group. The laboratory conducting the study concurs with that opinion.

JITF CST 9 asserts that none of the information contained within this notice constitutes confidential business information.

If you have any questions, please contact me by phone at (202) 772-4932.

Sincerely,

James Messina
Authorized Representative of
Joint Inerts Task Force CST 9

cc: FIFRA 6(a)(2)
JITF CST 9
Angelina Duggan, Exponent
Michela Dall'Osto, Exponent